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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,147	06/30/2003	Philippe Despres	239786US0CIP	8168

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EXAMINER	
WAX, ROBERT A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,147	DESPRES ET AL.	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20 and 22-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to polypeptide and pharmaceutical composition, classified in class 514, subclass 15.

II. Claims 6-16, drawn to polynucleotide, vector and host cell, classified in class 435, subclass 252.

III. Claim 17, drawn to antibody, classified in class 530, subclass 387.1.

IV. Claim 20, drawn to a method of screening for molecules capable of modulating apoptosis (method of use of polypeptide), classified in class 435, subclass 7.1.

V. Claim 22, drawn to a direct detection method of a flavivirus infection, classified in class 435, subclass 7.1

VI. Claim 23, drawn to a method of serological detection of a flavivirus infection, classified in class 435, subclass 7.1.

VII. Claims 24, 25, 27 and 28 (assuming that claim 28 was meant to depend from claim 27), drawn to pharmaceutical compositions of polynucleotide, classified in class 514, subclass 44.

VIII. Claims 26 and 29, drawn to a method of screening for molecules capable of modulating apoptosis, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. The polypeptide of group I is related to the polynucleotide of group II by virtue of the fact that the polynucleotide codes for the polypeptide. The polynucleotide molecule has utility for the recombinant production of the polypeptide in a host cell. Although the polynucleotide and the polypeptide are related, since the polynucleotide encodes the specifically claimed polypeptide, they are distinct inventions because the polypeptide product can be made by other, materially distinct processes, such as purification from the natural source. Further, polynucleotide can be used for processes other than the production of polypeptide, such as nucleic acid hybridization assays.

3. The polypeptide of group I is related to the antibody of group III by virtue of being the cognate antigen necessary for the production of antibody. Although the polypeptide and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because the polypeptide can be used in other, materially different processes from the production of antibody such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the polypeptide if it is a receptor. Further, a polypeptide and its cognate antibody are structurally and functionally distinct molecules with different amino acid compositions.

4. The polypeptide of Group I and the method of screening of Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In

the instant case the process for using the product as claimed can be practiced with another materially different product such as the polynucleotide encoding the polypeptide.

5. The polypeptide of group I is related to the method of using the antibody of group V by virtue of the fact that the polypeptide is encoded by the polynucleotide. The inventions are distinct, however, because, while the polypeptide is the cognate antigen necessary for the production of antibody, the polypeptide is not used in the method of use of the antibody and is not necessary for practice of said method. Therefore, the inventions are distinct.

6. The polypeptide of Group I and the method of detection of Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as the screening method of Group IV.

7. The polypeptide of group I is related to the pharmaceutical composition of group VII by virtue of the fact that the polynucleotide codes for the polypeptide. The polynucleotide molecule has utility for the recombinant production of the polypeptide in

a host cell. Although the polynucleotide and the polypeptide are related, since the polynucleotide encodes the specifically claimed polypeptide, they are distinct inventions because the polypeptide product can be made by other and materially distinct processes, such as purification from the natural source. Further, the pharmaceutical composition is capable of separate manufacture and sale and is used for different purposes from the polypeptide.

8. The polypeptide of Group I and method of use of polynucleotide of Group VIII are related because the polynucleotide to be detected encodes the polypeptide. Clearly, the polypeptide is not required for the practice of the screening method utilizing the polynucleotide, nor are they disclosed as capable of use together. Thus, notwithstanding the relationship, the two inventions are patentably distinct.

9. The polynucleotide of group II and the antibody of group III are related by virtue of the polypeptide that is encoded by the polynucleotide and necessary for the production of the antibody. However, the polynucleotide itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

10. The polynucleotide of group II is related to the method of using the polypeptide of group IV by virtue of the fact that the polypeptide is encoded by the polynucleotide. The inventions are distinct, however because the polynucleotide is not used in the method of

treating and is not necessary for the method of treating. Therefore, the inventions are distinct.

11. The polynucleotide of group II is related to the method of using the antibody of group V by virtue of the fact that the polypeptide that is the cognate antigen necessary for the production of antibody is encoded by the polynucleotide. The inventions are distinct, however, because the polynucleotide is not used in the method of use of the antibody and is not necessary for practice of said method. Therefore, the inventions are distinct.

12. The polynucleotide of group II is related to the method of using the polypeptide of group VI by virtue of the fact that the polypeptide is encoded by the polynucleotide. The inventions are distinct, however because the polynucleotide is not used in the method of detecting a flavivirus infection and is not necessary for the method of detecting a flavivirus infection. Therefore, the inventions are distinct.

13. The polynucleotide of Group II and the pharmaceutical compositions of Group VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the

subcombination as claimed because any of the polynucleotides of Group II would be usable in the pharmaceutical composition of Group VII but not all of them are required for any one composition. The subcombination has separate utility such as for making polypeptide encoded by the polynucleotide.

14. The polynucleotide of Group II and the screening method of Group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as manufacture of the polypeptide encoded by the polynucleotide.

15. The antibody of Group III and method of use of the polypeptide of Group IV, the method of use of the polypeptide of Group VI, the pharmaceutical composition of Group VII and the screening method of Group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Group III and the other methods do not require each other for their practice; have separate utilities, such as use of the antibody of Group III to detect flavivirus infection; are physically, chemically and

biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

16. The antibody of Group III and the detection method of Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as the complement of the polynucleotide that encodes the polypeptide.

17. The screening method of Group IV, detection method of Group V, the method of use of the polypeptide of Group VI, the pharmaceutical composition of Group VII and the screening method of Group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the screening method of Group IV and the other methods do not require each other for their practice; have separate utilities, such as use of the screening method of Group IV to detect modulators of apoptosis and the method of Group V detect flavivirus infection; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other.

These groups have acquired separate status in the art and separate fields of search.

18. The detection method of Group V, the method of use of the polypeptide of Group VI, the pharmaceutical composition of Group VII and the screening method of Group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the detection method of Group V and the other methods do not require each other for their practice; have separate utilities; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search.

19. The method of use of the polypeptide of Group VI, the pharmaceutical composition of Group VII and the screening method of Group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of use of the polypeptide of Group VI and the other methods do not require each other for their practice; have separate utilities, such as use of the method of use of the polypeptide of Group VI to detect flavivirus infection and the method of use of the polynucleotide of Group VIII to screen for modulators of apoptosis; are physically, chemically and

biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search.

20. The pharmaceutical composition of Group VII and the screening method of Group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the pharmaceutical composition of Group VII and the other method do not require each other for their practice; have separate utilities; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search.

21. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

22. A telephone call was not made to request an oral election to the above restriction requirement in view of the complexity of the restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

23. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

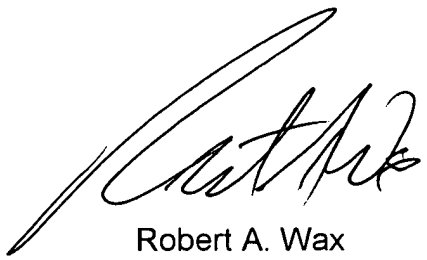
found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert A. Wax
Primary Examiner
Art Unit 1653

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